

Program and GMP Post-Award Administration of Grants

Mary Kirker

Chief Grants Management Officer

**The National Institute of Allergy and
Infectious Diseases (NIAID)**

Notice of Award

***YOUR OBLIGATION
IS TO READ AND ABIDE BY
THE
NOTICE OF AWARD***

Notice of Award

The NoA is a legally binding document and a grantee organization indicates acceptance of an NIH award and **its associated terms and conditions, including restrictions**, by spending \$1 U.S. of the awarded funds.

Example



Notice of Award
RESEARCH PROJECT COOPERATIVE AGREEMENT **Issue Date:** 05/09/2007
Department of Health and Human Services
National Institutes of Health
NATIONAL INSTITUTE OF ALLERGY AND INFECTIOUS DISEASES



Grant Number: 5U01AI

← **Grant number**

Principal Investigator(s):
JENNIFER F

Project Title: S.japonicum and pregnancy outcomes: an RCT

JENNY
RESEARCH ADMINISTRATOR
RHODE ISLAND HOSPITAL
593 EDDY STREET
PROVIDENCE, Rhode Island 029034923

Award e-mailed to: ORA@lifespan.org

Budget Period: 04/01/2007 – 03/31/2008

Project Period: 04/06/2006 – 03/31/2011

← **Budget period**

← **Project period**

← **Award amount**

Dear Business Official:

The National Institutes of Health hereby awards a grant in the amount of \$711,400 (see "Award Calculation" in Section I and "Terms and Conditions" in Section III) to RHODE ISLAND HOSPITAL (PROVIDENCE, RI) in support of the above referenced project. This award is pursuant to the authority of 42 USC 241 31 USC 6305 & 6306 and is subject to the requirements of this statute and regulation and of other referenced, incorporated or attached terms and conditions.

Award Calculation (U.S. Dollars)

Salaries and Wages
Fringe Benefits
Supplies
Travel Costs
Other Costs
Consortium/Contractual Cost

\$33,707
\$9,905
\$960
\$2,400
\$3,419
\$929,540

Example

Federal Direct Costs
Federal F&A Costs
Approved Budget
Federal Share
TOTAL FEDERAL AWARD AMOUNT

\$979,931
\$87,425
\$1,067,356
\$1,067,356
\$1,067,356

Amount you
can use

Amount of
money awarded

AMOUNT OF THIS ACTION (FEDERAL SHARE)

\$0

SUMMARY TOTALS FOR ALL YEARS		
YR	THIS AWARD	CUMULATIVE TOTALS
1	\$1,067,356	\$1,067,356
2	\$1,043,196	\$1,043,196
3	\$1,072,674	\$1,072,674
4	\$1,103,041	\$1,103,041
5	\$1,134,182	\$1,134,182
6	\$1,166,265	\$1,166,265
7	\$1,199,303	\$1,199,303

Recommended future year total cost support, subject to the availability of funds and satisfactory progress of the project.

Fiscal Information:

CFDA Number: 93.855
EIN: 1042103580C5
Document Number: UAI069412A
Fiscal Year: 2007

IC	CAN	2007	2008	2009	2010	2011	2012	2013
AI	8467027	\$1,067,356	\$1,043,196	\$1,072,674	\$1,103,041	\$1,134,182	\$1,166,265	\$1,199,303

Recommended future year total cost support, subject to the availability of funds and satisfactory progress of the project.

NIH Administrative Data:

PCC: A14D / OC: 414L / Processed: Anonymous 05/07/2007

SECTION II – PAYMENT/HOTLINE INFORMATION – 1U01AI069412-01 REVISED

For payment and HHS Office of Inspector General Hotline information, see the NIH Home Page at <http://grants.nih.gov/grants/policy/awardconditions.htm>

Notice of Award

- Applicable terms and conditions of award are determined at NIH's discretion and not subject to appeal.
- Once the award is accepted by the grantee, the contents of the NoA are binding on the grantee unless and until modified by a Revised Notice of Award signed by the GMO.

Terms of Award

Notice of Award Sections III & IV

- Terms of Award accompany every NoA issued
- They include general as well as grant specific terms.
- They can either be informational, or restrictive.

Terms of Award

Notice of Award Sections III & IV

- General Terms:

- The NIH Grants Policy Statement is a term of award and summarizes all policy requirements that serve as terms and conditions of NIH grant awards.

- The NIH Grants Policy Statement is available on the World Wide Web at:

http://grants.nih.gov/grants/policy/nihgps_2003/index.htm

SECTION III – TERMS AND CONDITIONS – 1U01AI069412-01

This award is based on the application submitted to, and as approved by, NIH on the above-titled project and is subject to the terms and conditions incorporated either directly or by reference in the following:

- a. The grant program legislation and program regulation cited in this Notice of Award.
- b. The restrictions on the expenditure of federal funds in appropriations acts to the extent those restrictions are pertinent to the award.
- c. 45 CFR Part 74 or 45 CFR Part 92 as applicable.
- d. The NIH Grants Policy Statement, including addenda in effect as of the beginning date of the budget period.
- e. This award notice, INCLUDING THE TERMS AND CONDITIONS CITED BELOW.

**The NIH Grants
Policy Statement
must be followed**

(See NIH Home Page at '<http://grants.nih.gov/grants/policy/awardconditions.htm>' for certain references cited above.)

This grant is awarded under the terms and conditions of the Federal Demonstration Partnership Phase IV.

Carry over of an unobligated balance into the next budget period requires Grants Management Officer prior approval.

Treatment of Program Income:

Additional Costs

Terms of Award

Notice of Award Sections III & IV

- Grant Specific Administrative Terms:
 - There are 2 types of restrictive terms:
 1. Restricts the use of funds for a purpose (Example: for purchasing a specific piece of equipment)
 2. Restricts a general or specific amount of funds that can not be used at all until issues or assurances have been resolved.
- Applicable terms and conditions of award are determined at NIH's discretion and not subject to appeal.
- Once the award is accepted by the grantee, the contents of the NoA are binding on the grantee unless and until modified by a Revised Notice of Award signed by the GMO.

Terms of Award

Notice of Award Sections III & IV

Grant specific administrative terms on the NoA may include:

- Issues related to funding, including funding restrictions

- NIAID required clinical terms

- Special Requirement of the Institute (identified Key Personnel; accrual requirements for future funding). Often these requirements are in the solicitation (RFA).

RESTRICTION: This award is issued without a Federalwide Assurance of Protection (FWA) for Human Subjects for the grantee institution. The grantee institution must file a Federalwide Assurance with the Office for Human Research Protections (OHRP) within 60 days of the issue date of this award. Information on and instructions for submitting and negotiating a Federalwide Assurance are available at the OHRP website (<http://www.hhs.gov/ohrp/>). The grantee institution must provide the awarding component with the submission date of required Assurance documents to OHRP. The grantee is then responsible for notifying the NIH awarding component when OHRP has approved the Assurance and for providing the NIH awarding component with a certification of Institutional Review Board (IRB) approval.

The grantee institution may conduct only activities that are clearly severable and independent from activities that involve human subjects until OHRP has approved an Assurance and the NIH awarding component has received and accepted the grantee institution's certification of IRB approval.

No funds may be drawn down from the payment system and no obligations may be made against Federal funds for research involving human subjects for any period not covered by both an OHRP-approved Federalwide Assurance and an IRB approval consistent with 45 CFR Part 46.

Annual Financial Status Reports (Form SF-269) are required from foreign grantees. (NIH Guide, April 6, 1999). The Financial Status Report form is available at: <http://grants.nih.gov/grants/forms.htm>

If the grantee institution is registered to do business in the NIH Commons, the Financial Status Report (FSR) should be submitted electronically through the NIH Commons available at <https://commons.era.nih.gov/commons/>. Additional information on electronic submission of FSRs is available at the Commons Homepage or by contacting the eRA Helpdesk at: commons@od.nih.gov or (866) 504-9552.

Paper submission of Financial Status Reports may be mailed to:

ATTN: Joyce Lee
Government Accounting Branch
Office of Financial Management
National Institutes of Health
2115 East Jefferson Street, MSC 8500
Ste. 4B432

Failure to comply with the above requirements can result in suspension and/or termination of this award, withholding of support, audit disallowances, and/or other appropriate action.

See the NIH Grants Policy Statement, December 2003, (http://grants2.nih.gov/grants/policy/nihgps_2003/NIHGPs_Part5.htm), pages 54-56 for specific requirements related to the protection of human subjects, which are applicable to and a term and condition of this award.

This award is subject to the Clinical Terms of Award included in Monitoring of Clinical Trials and Studies - NIAID (see NIH Guide for Grants and Contracts, July 8, 2002, NOT AI-02-032). These terms and conditions are hereby incorporated by reference, and can be accessed via the following World Wide Web address: <http://www.niaid.nih.gov/ncn/pdf/clinterm.pdf> All submissions required by the NIAID Clinical Terms of Award must be forwarded electronically or by mail to the responsible NIAID Program Official identified on this Notice of Grant Award.

Temporarily
restricted use of
funds for Human
Subject research
until FWA approved

Addressed the
need for
Financial Status
Reports

Referenced the NIAID
rules on Human Subject
Research

Terms of Award

Notice of Award Sections III & IV

- Programmatic Terms of Award are a part of all Cooperative Agreements “U” awards
- They are specific to the grant solicitation (RFA/FOA) and/or award.

They are organized in the following sections:

- Applicability
- Awardee Rights and Responsibilities
- NIAID Staff Responsibilities
- Collaborative Responsibilities
- Arbitration

Programmatic Terms of Award

This award is subject to the Terms and Conditions of Award as set forth in Section VI: Award Administrative Information of RFA AI-05-002, NIH Guide to Grants and Contracts, 02/10/2005. These special terms and conditions are incorporated in this award by reference.

Copies of the RFA/PA/PAR may be accessed at the following Internet address:
<http://www.nih.gov/grants/guide/index.html>

2.A. Cooperative Agreement Terms and Conditions of Award

The following special terms of award are in addition to, and not in lieu of, otherwise applicable OMB administrative guidelines, HHS grant administration regulations at 45 CFR Parts 74 and 92 (Part 92 is applicable when State and local Governments are eligible to apply), and other HHS, PHS, and NIH grant administration policies.

The administrative and funding instrument used for this program will be the cooperative agreement U01, an "assistance" mechanism (rather than an "acquisition" mechanism), in which substantial NIH programmatic involvement with the awardees is anticipated during the performance of the activities. Under the cooperative agreement, the NIH purpose is to support and stimulate the recipients' activities by involvement in and otherwise working jointly with the award recipients in a partnership role; it is not to assume direction, prime responsibility, or a dominant role in the activities. Consistent with this concept, the dominant role and prime responsibility resides with the awardees for the project as a whole, although specific tasks and activities may be shared among the awardees and the NIH as defined above.

Terms of Award

- What other information is provided in the terms and conditions?

This award is based on the application submitted to, and as approved by, the NIH on the above-titled project and is subject to the terms and conditions incorporated either directly or by reference in the following:

- a. The grant program legislation and program regulation cited in this Notice of Grant Award.
- b. The restrictions on the expenditure of federal funds in appropriations acts, to the extent those restrictions are pertinent to the award.
- c. 45 CFR Part 74 or 45 CFR Part 92 as applicable.
- d. The NIH Grants Policy Statement, including addenda in effect as of the beginning date of the budget period.
- e. This award notice, INCLUDING THE TERMS AND CONDITIONS CITED BELOW.

(see NIH Home Page at <http://grants.nih.gov/grants/policy/awardconditions.htm> for certain references cited above.)

An unobligated balance may be carried over into the next budget period without Grants Management Officer prior approval.

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This grant is subject to Streamlined Noncompeting Award Procedures (SNAP).

Automatic Carryover

SNAP Award

Bumps in the Road

Issues that have either delayed an award or affected the ability to use funds:

- Late application – late documents
- Incomplete information, e.g. other support, appropriate answers to SNAP questions
- Large Unobligated Balances
- Assurances/Certifications

Due Dates

Applications/ Forms	Budget Period End Date	Due Date
Progress Report PHS 2590	12/31/2007	11/01/2007
Financial Status Report	12/31/2007	03/31/2008
IRB Approval		Due Annually
Federalwide Assurance (FWA)		Renew Every 3 Years
Animal Assurance		Renew Every 5 Years

PHS 2590 Non-competing Progress Report

- **SNAP:**

- Must answer three SNAP questions at the beginning of the progress report:
 - ***Has there been a change in the other support of key personnel since the last reporting period?***
 - If the answer is yes, complete Other Support Information
 - ***Will there be, in the next budget period, a significant change in the level of effort for the PI or other personnel designated on the Notice of Grant Award from what was approved for this project?***
 - A significant change is a 25% reduction in time devoted to a grant. So if the original effort was 4 months the a significant change would be new effort of 3 months or less effort

PHS 2590 Non-competing Progress Report

- **SNAP:**

- Must answer three SNAP questions at the beginning of the progress report:
 - ***Is it anticipated that an estimated unobligated balance (including prior year carryover) will be greater than 25 percent of the current year's total budget?***
 - If yes, provide an explanation of why there is a balance and how it will be spent if carried forward into the next budget period
 - NIAID may require additional information. Failure to provide the information may result in a delay in an award.

Human Subjects Requirements

Institutional Review Board (IRB) Approval

- According to 45 CFR 46.103(b) and (f) <http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.htm#46.103> the Grantee Institution must certify to the awarding agency that the application or proposal for research has been reviewed and approved by an IRB designated in the assurance. The primary institution is responsible to have someone (of their IRB committee) review the entire grant application for support.

Human Subjects Requirements

Institutional Review Board (IRB) Approval

- Certification of IRB approval – needs approval every year
- IRB approvals should reference the Grant Number, Principal Investigator and Title of Application.



QUESTIONS?

NIH Websites

- NIH Grants Policy Statement
http://grants2.nih.gov/grants/policy/nihgps_2003/index.htm
- NIH Guide Notice NOT-OD-00-09, Process for E-Mail Submissions of Prior Approvals for NIH Grants and Cooperative Agreements
<http://grants.nih.gov/grants/guide/notice-files/NOT-OD-00-009.html>
- NIH Guide Notice NOT-OD-06-054, NIH Announces Change in Business Process: Replacing Principal Investigator Signature on Grant Applications, Progress Reports, and Prior Approval Requests with an Institutional Compliance Requirement <http://grants.nih.gov/grants/guide/notice-files/NOT-OD-06-054.html>

NIAID Websites

- **NIAID Division of Extramural Activities--Standard Operating Procedures for Carryover Requests** <http://www.niaid.nih.gov/ncn/sop/carryover.htm>
- **NIAID Division of Extramural Activities—Standard Operating Procedure for Expanded Authorities or Federal Demonstration Partnership** <http://www.niaid.nih.gov/ncn/sop/ea.htm>
- **NIAID Division of Extramural Activities—Standard Operating Procedure for Prior Approvals for Post-Award Grant Actions SOP** <http://www.niaid.nih.gov/ncn/sop/priorapproval.htm>